

Package leaflet: Information for the patient

Zirtene Allergy 10 mg film-coated tablets cetirizine dihydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet:

1. What Zirtene Allergy is and what it is used for
2. What you need to know before you take Zirtene Allergy
3. How to take Zirtene Allergy
4. Possible side effects
5. How to store Zirtene Allergy
6. Contents of the pack and other information

1. What Zirtene Allergy is and what it is used for

Cetirizine dihydrochloride is the active ingredient of Zirtene Allergy. Zirtene Allergy is an anti-allergy medication.

In adults and children aged 6 years and above, Zirtene Allergy is indicated:

- for the relief of symptoms of hay fever (seasonal allergic rhinitis) and allergies such as dust or pet allergies (perennial allergic rhinitis), such as sneezing, itchy, runny and blocked nose, red and watery eyes.
- for the relief of chronic nettle rash (chronic idiopathic urticaria).

2. What you need to know before you take Zirtene Allergy

Do not take Zirtene Allergy

- if you are allergic to cetirizine dihydrochloride or any of the other ingredients of this medicine (listed in section 6) or to hydroxyzine or to piperazine derivatives (closely related active substances of other medicines).
- if you have a severe kidney disease and are undergoing dialysis due to severe kidney failure

Warnings and precautions

Talk to your doctor or pharmacist before taking Zirtene Allergy

- if you have kidney problems. You may need to take a lower dose. The new dose will be determined by your doctor.
- if you have problems passing urine (e.g. spinal cord problems or prostate or bladder problems).
- if you have epilepsy or are at risk of convulsions, you should ask your doctor for advice.

If you need a skin (allergy) test, tell the doctor you are taking these tablets, as antihistamines can effect skin test results. You will need to stop treatment at least three days before the test.

Children

This medicine is not recommended in children under 6 years.

Other medicines and Zirtene Allergy

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Due to the profile of cetirizine, no interactions with other medicines are expected.

Zirtene Allergy with alcohol

It is recommended to avoid consumption of alcohol while taking this medicine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

As with other medicines, use of Zirtene Allergy should be avoided by pregnant women. Accidental use of this medicine by a pregnant woman should not cause any harmful effects on the foetus. Nevertheless, the use of this medicine should be discontinued once you find out you are pregnant.

You should not take Zirtene Allergy if you are breast-feeding because cetirizine passes into breast milk.

Driving and using machines

Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Zirtene Allergy at the recommended dose.

If you feel tired, less able to concentrate or think clearly, or feel unwell, after you have taken Zirtene you should not drive, take part in activities that may be dangerous or operate machinery. You should not exceed the recommended dose.

Zirtene Allergy contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicinal product.

3. How to take Zirtene Allergy

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and adolescents above 12 years old:

The recommended dose is 10 mg once daily as 1 tablet.

Children between 6 and 12 years old:

The recommended dose is 5 mg twice daily (For this dosing regimen; a different formulation should be used).

Patients with moderate to severe kidney problems:

The recommended dose for patients with moderate kidney problems is 5 mg once daily.

The recommended dose for patients with severe kidney problems is 5mg once every two days. For these dosing regimens; a different formulation should be used.

If you suffer from kidney disease, please contact your doctor or pharmacist before taking Zirtene Allergy.

If you feel that the effect of Zirtene Allergy is too weak or too strong, please consult your doctor.

The tablets need to be swallowed with a glass of liquid. The score line is only there to help you break the tablet if you have difficulty in swallowing it whole.

Duration of treatment:

The duration of treatment depends on the type, duration and course of your complaints and is determined by your doctor.

If you take more Zirtene Allergy than you should

If you think you have taken an overdose of Zirtene Allergy please inform your doctor.

Your doctor will then decide what measures, if any, should be taken.

After an overdose, the side effects described below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, ailing, dilating of pupil, itching, restlessness, sedation, sleepiness, loss of consciousness, abnormal rapid heart rate, tremors and not being able to pass urine have been reported.

If you forget to take Zirtene Allergy

Do not take a double dose to make up for a forgotten tablet.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following stop taking Zirtene Allergy and contact your doctor immediately or go to the nearest hospital emergency department:

Rare (may affect up to 1 in 1,000 people)

Convulsions (fits)

Very rare (may affect up to 1 in 10,000 people)

Swelling of the face, throat, tongue or mouth or difficulty breathing, rash, itching, as this may be a sign of a serious allergic reaction

Uncontrolled movements of the eyes (oculogyric crisis)

Not known (frequency cannot be estimated from the available data)

Thoughts of harming or killing yourself (suicidal ideation)

Trouble completely emptying your bladder when passing urine (urinary retention)

Other side effects are:

Common (may affect up to 1 in 10 people)

- fatigue (feeling tired)

- dry mouth
- feeling sick/dizziness
- headache
- somnolence (sleepiness)
- pharyngitis (sore throat)

Uncommon (may affect up to 1 in 100 people)

- abdominal pain
- diarrhoea
- asthenia (feeling weak)
- malaise (generally feeling unwell)
- paraesthesia (numbness or tingling of the skin)
- agitation
- pruritus (itching)
- rash

Rare (may affect up to 1 in 1,000 people)

- tachycardia (fast heart beat)
- oedema (swelling)
- other allergic reactions
- liver function abnormal (this will be seen in a blood test)
- weight gain
- aggression
- confusion
- depression
- hallucinations (seeing, feeling or hearing things that are not there)
- insomnia (problems with sleeping)
- urticaria (hives)

Very rare (may affect up to 1 in 10,000 people)

- thrombocytopenia (low levels of blood platelets) which increases the risk of bleeding or bruising
- eye accommodation disorder (inability of the eye to automatically change focus)
- blurred vision
- syncope (fainting)
- dyskinesia (involuntary movements)
- dystonia (abnormal, repeated twisting movements of the muscles that may be painful)
- tremor
- dysgeusia (altered taste)
- tics (uncontrolled repeated twitching movements)
- loss of control of passing urine (bed wetting, pain when passing urine)
- fixed drug eruption (appearance of red or blistered skin in the same place after taking this medicine)

Not known (frequency cannot be estimated from the available data)

- amnesia
- memory problems
- increased appetite

- vertigo (spinning sensation)

Additional side effect seen in children aged 6 months to 12 years

Common (may affect 1 in 10 people)

- rhinitis

Side effect seen more commonly in children aged 6 months to 12 years

Common (may affect 1 in 10 people)

- diarrhoea

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zirtene Allergy

Keep out of the sight and reach of children.

Do not use Zirtene Allergy after the expiry date which is stated on the carton and blister after EXP. The expiry date is the last day of that month

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Zirtene Allergy contains

- The active substance is cetirizine dihydrochloride. Each film-coated tablet contains 10 mg cetirizine dihydrochloride.

- The other ingredients are lactose monohydrate (see section 2 “Zirtene Allergy contains lactose”) pregelatinised maize starch, povidone, magnesium stearate. The coating includes hypromellose, macrogol and titanium dioxide (E171).

What Zirtene Allergy looks like and contents of the pack

White, capsule shaped film-coated tablets with a score line and marked ‘CZ 10’ on one side and ‘G’ on the other. Zirtene Allergy is supplied in foil blister packs with 7 or 10 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

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